Section II (Remarks)

A. Summary of Amendment to the Claims

By the present Amendment, claims 1 and 2 have been amended and claims 3 and 6 have been cancelled, without prejudice. No new matter within the meaning of 35 U.S.C. §132(a) has been introduced by the foregoing amendments.

The amendments made herein are fully consistent with and supported by the originally-filed disclosure of this application. Specifically, the amendments to claim 1 are supported by original claims 2, 3, and 6.

In view of the finality of the May 15, 2009 Office Action and to ensure substantive consideration of this response, a Request for Continued Examination is concurrently submitted herewith, together with payment of the appertaining RCE fees (see *infra*, "Conclusion").

Thus, upon entry of the amendments, claims 1, 2, 4, 5, and 7-13 will be pending, of which claims 9-13 are withdrawn.

B. Objection to the Claims

In the Office Action mailed May 15, 2009 the examiner objected to the misspelling of the word "calls" in part (e) of claim 1. The examiner's attention is respectfully drawn to claim 1 in Section I above. As amended, claim 1 no longer contains the misspelled word "calls." Withdrawal of the objection is respectfully requested.

C. Rejection of the Claims Under 35 U.S.C. § 112, 1st paragraph – Written Description

In the Office Action mailed May 15, 2009 the examiner rejected claims 1, 2 and 4-8 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Applicants respectfully draw the examiner's attention to Section I above, where claim 1 has been amended.

The examiner rejects claim 1 for containing the language "one or more mitogenically stimulated surface markers." The examiner alleges that "[t]he claims do not require that the 'mitogenically stimulated surface markers' possess any particular conserved structure or other disclosed

distinguishing feature." (Office Action mailed May 15, 2009, p. 3.)

As amended, claim 1 now recites a method of diagnosis, by means of analysis of a patient sample and "a mitogenically stimulated surface marker…" (emphasis added). The preamble now recites a single marker and the amended steps of the claim specify the surface maker CD69. This surface marker is described in the specification in detail, e.g. at page 4, lines 16-35, the Examples and original claim 3.

It is respectfully submitted that amended claim 1 meets the written description requirement of 35 U.S.C. §112, first paragraph. Claims 2, 4, 5, 7, and 8, dependent from claim 1, correspondingly meet the written description requirement.

D. Rejection of the Claims Under 35 U.S.C. § 112, 1st paragraph – Enablement

In the Office Action mailed May 15, 2009 the examiner rejected claims 1-8 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Applicants respectfully traverse the rejection.

Initially, the examiner's attention is again respectfully drawn to Section I above. By the amendments indicated therein, claim 1 has been amended to recite lymphocytes as the specific cells, CD69 as the specific surface marker and PHA or PWM as the mitogenic agent. As stated above, all amendments are supported by the specification, as originally filed. It is respectfully submitted that the method recited by amended claim 1 and claims 2, 4, 5, 7, and 8, dependent therefrom, meets the enablement requirements of 35 U.S.C. §112, first paragraph.

Specifically, the examiner alleges that the method is not enabled for the step of detection that a patient is suffering from Alzheimer's disease or predisposition therefore "if the stimulation index… is at least 10, with a maximum of 100." The examiner alleges that the guidance in the specification "…is merely speculative and…does not provide guidance to one of ordinary skill in the art that the method can be performed with reasonable expectation of success of diagnosing Alzheimer's disease." (Office Action mailed May 15, 2009, p. 7.)

A determination of enablement under 35 U.S.C. §112, first paragraph is based on an evaluation of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the relevant art to make and use the claimed

invention without "undue experimentation." Applicants assert that the disclosure of the present application is so enabling. In support of such assertion, applicants submit a Declaration under 37 C.F.R. §1.132 by Inventor Thomas Arendt.

In his declaration, Dr. Arendt describes a study performed including 21 patients with Alzheimer's disease (AD study group). The samples were prepared according to the example of the specification (pages 7-9) and the stimulation index was calculated as the quotient of the number of lymphocytes bearing CD69 before mitogenic stimulation and after mitogenic stimulation. It is seen in the results provided in Table 1 that a stimulation index of more than 10 is indicative for Alzheimer's disease as described in the application. Therefore, the claimed method is enabled by the originally filed application.

In the study described by Dr. Arendt, the classification of the test persons in the Alzheimer's patient group or the control group was made according to the ICD-10 research criteria. It is noted, however, that an accurate diagnosis of Alzheimer's disease is only possible post-mortem when brain material is available and can be examined histologically. The ICD-10 is a standardized diagnostic process for physicians with an accuracy of from about 80% to about 95%. The data of the enclosed declaration show that the test results achieved using the claimed method are largely in accordance with the results, *i.e.*, classification, after the established ICD-10 diagnostic procedure. Therefore, the claimed method is a suitable additional diagnostic tool for Alzheimer's disease.

Thus, the claimed method provides a quick and simplified procedure for a preliminary diagnosis of Alzheimer´s disease from only a single sample with a high predictive value. The claimed method meets the enablement requirements of 35 U.S.C. §112, first paragraph. Withdrawal of the rejection is therefore respectfully requested.

CONCLUSION

Based on the foregoing, all of applicants' pending claims 1, 2, 4, 5, 7, and 8 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

The time for responding to the May 15, 2009 Office Action without extension was set at three months, or August 15, 2009. Applicants hereby request a three month extension of time under 37

C.F.R. § 1.136 to extend the deadline for response to and including November 15, 2009. Payment of the $960.00 fee (extension fee of $555.00 specified in 37 C.F.R. § 1.17(a)(3) and the RCE fee of $405.00), as applicable to small entity, is being made by on-line credit card authorization at the time of EFS submission of this Response. Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the examiner is requested to contact the undersigned attorneys at (919) 419-9350 to discuss same.

Respectfully submitted,

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